

REMARKS

Applicants respectfully solicit favorable reconsideration and allowance.

Applicants have extended the response date by concurrently filed Petition for an Extension of Time.

I. Traversing the anticipation rejections.

The Examiner "bears the initial burden, on review of the prior art . . ., of presenting a *prima facie* case of unpatentability," In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992), under the cited provision of Section 102. Applicants submit there is no such *prima facie* case of anticipation.

The novelty provisions under 35 U.S.C. §102 state an applicant is entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Anticipation under § 102 can only arise when a prior art reference discloses each and every claim limitation either expressly or inherently. Any allegation of inherency must be supported by facts demonstrating the purported inherent matter was necessarily, inevitable, and always the outcome because probability, possibility and the like do not satisfy the heavy evidentiary burden required for anticipation.

A. Claims 1-9 Define Novel Inventions over Ritter et al., USP 6,086,863.

Applicants traverse the rejection of Claims 1-9 under 35 U.S.C. 102 (b) as being anticipated by Ritter et al (US 6,086,863; hereinafter referred to as Ritter).

Claims 1 to 3 of the present invention, which are the independent claims in this application, all recite a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C. Accordingly, it is apparent that the process claimed in the present invention is characterized and also made distinct from others (including all the references cited by the Office Action) by immersion of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C.

This is facially the case inasmuch as the Office Action which does not recite Ritter as disclosing carbonated warm water or carbon dioxide concentration and temperature thereof

Instead, Ritter discloses and claims therapeutic compositions of microspheres for application to wounds and/or lesions for accelerating wound healing and muscle generation. On the other hand, as described above, the present invention discloses and claims a vascularization therapy, which is a process rather than a composition of microspheres.

Moreover, Ritter does not apparently disclose an alleged invention relating to or even particularly drawn to vascularization therapy. If it is accepted that the description in Ritter; i.e. "Essentially, all wound healing involves the repair or replacement of damaged tissues including but not limited to skin, muscle, neurologic tissues, bone, soft tissue, internal organs or vascular tissue," makes Ritter to encompass the present invention as stated in the Office Action, all the inventions related to wound/lesion healing can be encompassed by Ritter, which is clearly not the case.

Furthermore, Ritter does not mention carbonated warm water or carbon dioxide concentration and temperature thereof at all in their specification. Thus, Ritter does not

teach or even suggest a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 1 and 3 and those dependent therefrom (i.e., Claims 4-9) under 35 U.S.C. 102(b) as being anticipated by Ritter.

B. Claims 1-9 define novel inventions over Martin et al., USP 5,062,183.

Applicants respectfully traverse the rejection of Claims 1-9 under 35 U.S. C. §102 (b) over Martin et al (US 5,602,183; hereinafter Martin et al. or '183).

As described earlier, all the claims in the present application recite a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C.

Applicants respectfully submit that Martin et al. does not disclose and does not describe an alleged invention related to vascularization therapy, and thus does not anticipate Applicants' claims. Indeed, this follows because the Office Action is conspicuous since it does not cite to any passage in Martin et al. as describing or disclosing, for instance, carbonated warm water or carbon dioxide concentration and temperature thereof at all.

Rather, Martin et al. discloses therapeutic dermatological-wound healing compositions useful to minimize and treat diaper dermatitis and also methods for preparing and using the therapeutic dermatological-wound healing compositions.

Once again as is the case with Ritter, Martin et al do not mention carbonated warm water or carbon dioxide concentration and temperature thereof at all in their specification. Thus, Martin et al do **not teach or even suggest** a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 1 and 3 and those dependent therefrom (i.e., Claims 4-9) under 35 U.S.C. 102(b) over Martin et al.

II. Traversing the Obviousness Rejection(s).

The Examiner “bears the initial burden, on review of the prior art . . . , of presenting a *prima facie* case of unpatentability,” In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992), under the cited provision of Section 102. Applicants submit there is no *prima facie* case of obviousness as to the claims herein.

Obviousness is considered under 35 U.S.C. §103(a) in view of Graham v. John Deere, 383 U.S. 1 (1966) and Alza Corp. v. Mylan Labs., Appeal No. 06-1019 (Fed. Cir. Sept. 6, 2006) (exhaustively explaining the Graham analysis), mindful as well of the Federal Circuit’s other recent discourses on the obviousness determination, *see, e.g.*, DyStar Textilfarben GmbH v. C. H. Patrick Co., 464 F.3d 1356 (Fed. Cir. 2006). The statute requires a careful, factual analysis to ascertain whether the differences between the subject matter to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains, without regard to how the invention was actually ‘made.’ 35 U.S.C. §103(a).

Where, as here, claims were rejected over a combination of alleged prior art, it is incumbent on the party asserting invalidity to demonstrate factual basis that would have made it obvious to person of ordinary skill in the art to combine the alleged prior art. However, it is a basic principle that a rejection cannot be predicated on the mere identification of individual components of claimed limitations. There must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998); and *see also* In re Werner Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000). That is, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification" Ex parte Metcalf, 67 USPQ2d 1633, 1635 (BOPI 2003), quoting in re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992). "[I]t is incumbent upon the examiner to identify some suggestion to combine the references or make the modification." Ex parte Askman, Appeal No. 96-1548 (June 10, 1999) at page 5, quoting In re Mayne, 104 F.3d 1339, 1342 (Fed. Cir. 1997). The factual basis for an alleged suggestion "cannot 'be resolved on subjective belief and unknown authority.'" Ex parte Metcalf, 67 USPQ2d at 1635, quoting In re Lee, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002).

When an alleged prior art patent, including drawings, is silent on a quantitative relationship, rejections assuming the existence of any such quantitative relationship are undermined, and should be reconsidered, or otherwise is prone to being reversed.

Hockerson-Halberstadt Inc. v. Avia Group International Inc., 58 USPQ2d (BNA) 1487, 1491 (Fed. Cir. 2000); Ex parte Brown, 19 USPQ2d (BNA) 1609, 1612 (BOPI 1990) ("since the

prior art is silent as to this feature, we are unable to sustain the rejection ..."); Ex parte Isaksen 23 USPQ2d (BNA) 1001, 1006 (BOPI 2001), ("Forbes patent[s] are completely silent as to any sharpening effect and do not describe with any specificity what results ... magnetic treatment had on the razor blade edge," rejection reversed).

The problem addressed by the present method and the manner of its being addressed are neither disclosed nor would they have been suggested to a person of ordinary skill in the art by the reference. "A prima facie case of obviousness can be rebutted if the applicant ... can show 'that the art in any material respect taught away' from the claimed invention." In re Geisler, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (quoting In re Malagri, 499 F.2d 1297, 1303 (CCPA 1974)). A reference teaches away when a person of ordinary skill, upon reading the reference, would have been led in a direction divergent from the path that was taken by Applicants.

A. Claims 1-9 define Unobvious Inventions Over Annie et al. in view of Vyakarnam

Applicants respectfully submit claims 1-9 define unobvious inventions under 35 U.S.C. 103(a) over Annie et al (The FASEB Journal 1998, 12:1331; hereinafter referred to as Annie) in view of Vyakarnam et al (US 2001/0033857; hereinafter referred to as Vyakarnam).

Applicants respectfully submit that the references would not have been combined by a person of only ordinary skill in the art, and arguendo, even if they were, the combination would not have suggested the present claimed inventions to a person of only ordinary skill in the art.

As described earlier, all the claims in the present application recite a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C.

Applicants fail to understand why it is obvious to those skilled in the art to accomplish the present invention by combining Annie and Vyakarnam without any actual references to at least suggest a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C.

Annie reports *in vitro* formation of a human capillary-like network in a tissue-engineered skin equivalent. However, Annie does **not teach or even suggest** a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C

Vyakarnam does **not teach or even suggest** a vascularization therapy which involves immersing of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C. Rather, Vyakarnam discloses three-dimensionally interconnected open cell porous foams which have a gradient and which are alleged to be particularly suited for tissue engineering applications.

Indeed, neither Annie nor Vyakarnam mention carbonated warm water or carbon dioxide concentration and temperature thereof at all in their specification and this fact is supported by the Office Action itself. For instance, the reasoning as stated in the Office Action is conspicuously silent in that it does not recite carbonated warm water or carbon

dioxide concentration and temperature thereof at all by quoting Annie. Hockerson-Halberstadt, supra; Ex parte Brown, supra; Ex parte Isaksen, supra. Accordingly, there is no mention of effects and characteristics of the present invention in either of the references.

Moreover, it is respectfully submitted that both references relate to *in vitro* studies using tissue engineering methods and those which can be used for tissue engineering applications. On the other hand, the present application is already capable of being applied *in vivo* and at an individual level (not at a cell, a tissue, or an organ level) as clearly shown in the specification of the present application which used mice (for example, please refer to page 16, line 7).

Accordingly, the combination of Annie and Vyakarnam would not have been made, and even if made the present inventions would have been unobvious to the ordinary artisan over such combination.

Applicants therefore respectfully request withdrawal of the rejection of Claims 1 and 3 and those dependent therefrom (i.e., Claims 4-9) under 35 U.S.C. 103(a) as being unpatentable over Annie in view of Vyakarnam.

U.S. Appln. of Sakakibara et al.
Appln. No. 10/676,270
Response to September 26, 2006 Office Action

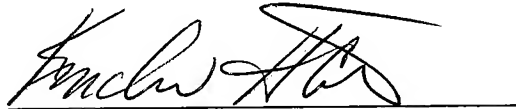
Attorney Docket: 7412/80657

Conclusion

Applicants courteously submit that they have responded in full to all matters raised in the Office Action, and demonstrated that their claims define novel and unobvious inventions for the reasons set forth. If the Examiner has any question, kindly telephone Applicants; legal representative.

Applicants respectfully solicit a Notice of Allowance.

Respectfully submitted,



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